Trochanteric Nail Implant System Patient Information Leaflet



Helping Surgeons Treat Their Patients Better[™]

Since its inception, Arthrex has been committed to one mission: Helping Surgeons Treat Their Patients Better. We are strategically focused on constant product innovation through scientific research, surgeon collaboration, and medical education to make less invasive surgical procedures simple, safer, and more reproducible. Each year, we develop more than 1000 new innovative products and procedures to advance minimally invasive orthopedics worldwide.

Arthrex has always remained a privately held company, which allows for the rapid evaluation of new technologies and ideas and the freedom to develop products and techniques that truly make a difference without economic considerations or compromise. Our experienced team of dedicated professionals represents a shared passion and commitment to delivering uncompromising quality to the healthcare providers who use our products and the millions of patients whose lives we impact.

The medical significance of our contributions serves as our primary benchmark of success and will continue into the future as the legacy of Arthrex.

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Anatomy and General Information

The greater trochanter is located at the top of the thigh bone (femur) and is the most prominent and widest part of the hip or pelvis. The proximal femur consists of the femoral head, the femoral neck, and the trochanteric region (including the greater and lesser trochanters). The proximal aspect of the femur articulates with the acetabulum of the pelvis to form the hip joint.

This leaflet contains information about your trochanteric nail implant. It may not contain all the information related to your specific procedure and if you have any questions, talk to your healthcare provider. All implants have risks and benefits. Follow your healthcare team's advice even if it differs from what is contained within this leaflet. Please read this leaflet carefully and refer to it in the future if needed.

The name and number of your nail implant can be found on your implant card. If a healthcare professional asks about your implant, please show them your implant card.

Device Description

The trochanteric nail implant system is comprised of the trochanteric nail, interlocking screw, and an end cap.

The trochanteric nail implant system is intended to treat stable and unstable proximal fractures of the femur including peritrochanteric, intertrochanteric and high subtrochanteric fractures and combinations of these fractures.

The trochanteric nail is available in 9, 10, 11, 12.5, and 14-mm diameters and provided in lengths of 20, 30, 33, 36, 39, 42, and 45 cm.

The interlocking screws are comprised of lag screws (solid, locking, telescoping), cortical screws, and anti-rotational screws. The screw family is 5.0 mm and 10.5 mm in diameter with lengths ranging from 20 mm to 125 mm (in 2mm or 5 mm increments).

The end caps are designed to prevent bone in growth in the distal portion of the nail implant for ease of removal. The end cap family ranges from 1 to 10 mm in size for various countersinking depths.

Material Specifications

Trochanteric nail: The trochanteric nail is manufactured from titanium alloy, (ASTM F136) which contains:

Titanium, (88.5 - 90.5%) Aluminum, (5.5 - 6.5%) Vanadium, (3.5 - 4.5%) Iron, (.25%) *Other materials may be present at trace levels.

Interlocking screws and end caps: The interlocking screws and end caps are manufactured from titanium alloy, (ASTM F136) which contains:

Titanium, (88.5 - 90.5%) Aluminum, (5.5 - 6.5%) Vanadium, (3.5 - 4.5%) Iron, (.25%) *Other materials may be present at trace levels.

The interlocking screws (telescoping lag screws only) include a spring manufactured from stainless steel (ASTM F138) which contains:

Iron, (64.2 - 59.5%) Chromium, (17 - 19%) Nickel, (13 - 15%) Molybdenum, (2.25 - .3%) *Other materials may be present at trace levels.

Indications

The trochanteric nail is intended to treat stable and unstable proximal fractures of the femur including peritrochanteric, intertrochanteric and high subtrochanteric fractures and combinations of these fractures. The long trochanteric nail is additionally indicated for subtrochanteric fractures, peritrochanteric fractures associated with shaft fractures, pathologic fractures (including prophylactic use) in osteoporotic bone of the trochanteric and diaphyseal areas, long subtrochanteric fracture, ipsilateral femoral fractures, proximal and distal non-unions and malunions and revisions procedures.

The ES trochanteric nail is intended to treat stable and unstable proximal fractures of the femur including peritrochanteric, intertrochanteric and high subtrochanteric fractures and combinations of these fractures.

*Extended Short (ES)

Contraindications

- 1. Insufficient quantity or quality of bone that would inhibit fusion of the joints and stabilization of the arthrodesis.
- 2. Blood supply limitations and previous infections, which may retard healing.
- **3**. Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made, and sensitivity ruled out prior to implantation.
- 4. Foreign Body Reactions. See Adverse Effects-Allergic Type Reactions.
- 5. Any active infection or blood supply limitations.
- 6. Conditions that tend to limit the patient's ability or willingness to restrict activities or follow directions during the healing period.
- 7. The use of this device may not be suitable for patients with insufficient or immature bone. The physician should carefully assess bone quality before performing orthopedic surgery on patients who are skeletally immature. The use of this medical device and the placement of hardware or implants must not bridge, disturb, or disrupt the growth plate.
- 8. Do not use for surgeries other than those indicated.
- 9. Patients with a high level of physical activity.

Risks/Adverse Effects

- 1. Infections, both deep and superficial.
- 2. Foreign body sensitivity.
- 3. Patient sensitivity to implant device materials must be considered prior to implantation.
- 4. Allergies and other reactions to device materials.
- 5. Wound hematoma and delayed wound healing.
- 6. Warning: This device contains an alloy of nickel. Persons with allergic reactions to these metals may suffer an allergic reaction to this implant. Prior to implantation, patients should be counseled on the materials contained in the device, as well as the potential for allergy/hypersensitivity to these materials.

Postoperative Care

Postoperative management is patient-specific and dependent on your doctor's assessment. Individual results will vary and not all patients will experience the same postoperative activity level or outcomes. Please be aware that surgery and recovery protocol may vary for each individual and any questions pertaining to the surgical procedure or postoperative protocol should be discussed with your surgeon.

Please call your doctor if:

- You experience loss of function
- You develop a fever greater than 38 °C (100.4 °F)
- Drainage continues from the site of your incision
- Your surgical site becomes more swollen, tender, and painful, with increased difficulty performing your exercises.

If you have difficulty breathing or develop severe pain or chest pain, call your local emergency care or report immediately to your local emergency room.

European emergency services – 112

North America emergency services – 911

Australia emergency services - 000

Precautions

- 1. An additional procedure may be required for the removal of the implant.
- 2. Please carefully review the postoperative instructions provided by the surgeon and nursing staff.
- **3**. Early weight and/or load bearing substantially increases implant loading and increases the risk of loosening, bending, or breaking the device.
- 4. Patients who are obese and/or non-compliant, as well as patients who could be predisposed to delayed union or non-union, must have auxiliary support.
- 5. Do not engage in unassisted weight-bearing activity without physician direction or medical release. Postoperative care and physical therapy should be structured to prevent the loading of the operative extremity until directed by the physician.

Life of the Device

- These devices are long-term fixation devices intended to aid in the normal healing process. They are not intended to bear the weight of the body in the presence of incomplete healing. If healing is delayed, or does not occur, the device may eventually break due to fatigue.
- 2. Information specific to your implant, such as lot number and unique device identifier are included on the implant card. This information is also located in the patient records kept by your healthcare provider.

Warnings

- 1. Caution: Federal law restricts this device to sale by or on the order of a physician.
- 2. This device is intended to be used by a trained medical professional.
- 3. \triangle An internal fixation device must never be re-used.
- 4. All metallic implant devices used for this surgical procedure should have the same composition properties.
- 5. Postoperatively and until healing is complete, fixation provided by this device should be considered as temporary and may not withstand weight bearing or other unsupported stress. The fixation provided by this device should be protected. The postoperative regimen prescribed by the physician should be strictly followed to avoid adverse stresses applied to the device.
- 6. Pre-operative and operating procedures, including knowledge of surgical techniques and proper selection and placement of the device, are important considerations in the successful utilization of this device. The appropriate Arthrex delivery system is required for the proper implantation of the device.
- 7. Any decision to remove the device should take into consideration the potential risk to the patient of a second surgical procedure. Device removal should be followed by adequate postoperative management.
- 8. Detailed instructions and limitations of this device are provided to the surgeon in addition to this patient information leaflet and your patient implant card.
- 9. Serious incidents should be reported to Arthrex Inc., or an in-country representative, and to the health authority where the incident occurred.
- 10. METAL SCREWS: Devices that have been implanted for a long period of time may require the use of screw removal instrumentation.
- 11. These are single-use devices. Reuse of this device could result in the failure of the device to perform as intended and could cause harm to the patient and/or user.

- 12. Over time, metallic implants may loosen, fracture, or cause pain after the bone fracture or osteotomy is healed. Removal of metallic implants is at the surgeon's discretion and if the supplemental fixation is not removed following the completion of its intended use, any of the following complications may occur: (1) Corrosion, with localized tissue reaction or pain; (2) Migration of implant position resulting in injury; (3) Risk of additional injury from postoperative trauma; (4) Bending, loosening, and/or breakage, which could make removal impractical or difficult; (5) Pain, discomfort, or abnormal sensations due to the presence of the device; (6) Possible increased risk of infection; and (7) Bone loss due to stress shielding. The surgeon should carefully weigh the risks versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid re-fracture.
- 13. Patient sensitivity to the device materials should be considered prior to implantation. See Adverse Effects.
- 14. The correct selection and placement of the implant is extremely important. The appropriate type and size should be selected for the patient. Failure to use the correct implant size or improper positioning may result in loosening, bending, cracking, or fracture of the device, bone, or both.
- 15. Bone fixation devices are neither intended to carry the full load of the patient nor intended to carry a significant portion of the load for extended periods of time. Device breakage or damage can occur when the implant is subjected to increased loading associated with delayed union, non-union, or incomplete healing. Improper insertion of the device during implantation can increase the possibility of loosening or migration.

MRI Safety Information

MRI, or Magnetic Resonance Imaging, is an imaging technique utilizing a strong magnetic field to produce detailed anatomical images. This section details the information that you should be aware of when receiving an MRI scan.

1. MR Conditional

Non-clinical testing and electromagnetic simulations demonstrated that the Trochanteric Nail Implant System is MR Conditional.

A patient with this device can be scanned safely in an MR system under the following conditions. Failure to follow these conditions may result in injury.		
Device Name	Trochanteric Nail Implant System	
Static Magnetic Field Strength (B ₀)	1.5-Tesla and 3-Tesla	
Maximum Spatial Field Gradient	25 T/m or 2,500 Gauss/cm	
RF (Radio Frequency) Excitation	Circularly Polarized (CP)	
RF (Radio Frequency)	Body Coil: See scan region limitations below.	
Transmit Coil Type	Local Coils: Head transmit-receive coil, no restrictions on local transmit-receive coils that the device is not within.	
Operating Mode	Normal Operating Mode	
Maximum Whole-Body SAR (Specific Absorption Rate)	See details below.	
Maximum Head SAR	3.2 W/kg (Normal Operating Mode)	
SAR and Scan Duration Limits Based on Anatomical Isocenter Landmarks* (for imaging with Body Coil)	Inferior to umbilicus 0.5 W/kg whole body average SAR for 60 minutes of continuous RF (a sequence or back to back series/ scan without breaks).	Superior to umbilicus 2 W/kg whole body average SAR for 60 minutes of continuous RF (a sequence or back to back series/ scan without breaks).



If information about a specific parameter is not included, there are no conditions associated with that parameter.



The person with a bone nail implant can safely undergo an MR exam only under very specific conditions. Scanning under different conditions may result in severe injury. Full MRI safety information is available in the MRI Safety Information section of this patient information leaflet, Directions for Use (https://edfu.arthrex.com) or by calling Arthrex customer service at \checkmark +1 800 934-4404.

Trochanteric Nail Implant System

Trochanteric Nail Implant Models

Consult your Trochanteric Nail System Implant Identification Card for information on the device type/model of the implant used in your procedure.

Product Description	Item Number
Short Trochanteric Nail, 9 mm x 20 cm x 125°	AR-9094-9-2025
Short Trochanteric Nail, 9 mm x 20 cm x 130°	AR-9094-9-2030
Short Trochanteric Nail, 10 mm x 20 cm x 125°	AR-9094-10-2025
Short Trochanteric Nail, 10 mm x 20 cm x 130°	AR-9094-10-2030
Short Trochanteric Nail, 11 mm x 20 cm x 125°	AR-9094-11-2025
Short Trochanteric Nail, 11 mm x 20 cm x 130°	AR-9094-11-2030
Short Trochanteric Nail, 12 mm x 20 cm x 125°	AR-9094-12-2025
Short Trochanteric Nail, 12 mm x 20 cm x 130°	AR-9094-12-2030
Short Trochanteric Nail, 13 mm x 20 cm x 125°	AR-9094-13-2025
Short Trochanteric Nail, 13 mm x 20 cm x 130°	AR-9094-13-2030
Long Trochanteric Nail, Left, 10 mm x 30 cm x 125°	AR-9094-10-3025L
Long Trochanteric Nail, Right, 10 mm x 30 cm, x 125°	AR-9094-10-3025R
Long Trochanteric Nail, Left, 10 mm x 33 cm x 125°	AR-9094-10-3325L
Long Trochanteric Nail, Right, 10 mm x 33 cm x 125°	AR-9094-10-3325R
Long Trochanteric Nail, Left, 10 mm x 36 cm x 125°	AR-9094-10-3625L
Long Trochanteric Nail, Right, 10 mm x 36 cm x 125°	AR-9094-10-3625R
Long Trochanteric Nail, Left, 10 mm x 39 cm x 125°	AR-9094-10-3925L
Long Trochanteric Nail, Right, 10 mm x 39 cm x 125°	AR-9094-10-3925R
Long Trochanteric Nail, Left, 10 mm x 42 cm x 125°	AR-9094-10-4225L
Long Trochanteric Nail, Right, 10 mm x 42 cm x 125°	AR-9094-10-4225R
Long Trochanteric Nail, Left, 10 mm x 45 cm x 125°	AR-9094-10-4525L
Long Trochanteric Nail, Right, 10 mm x 45 cm x 125°	AR-9094-10-4525R

Product Description	Item Number
Long Trochanteric Nail, Left, 10 mm x 30 cm x 130°	AR-9094-10-3030L
Long Trochanteric Nail, Right, 10 mm x 30 cm x 130°	AR-9094-10-3030R
Long Trochanteric Nail, Left, 10 mm x 33 cm x 130°	AR-9094-10-3330L
Long Trochanteric Nail, Right, 10 mm x 33 cm x 130°	AR-9094-10-3330R
Long Trochanteric Nail, Left, 10 mm x 36 cm x 130°	AR-9094-10-3630L
Long Trochanteric Nail, Right, 10 mm x 36 cm x 130°	AR-9094-10-3630R
Long Trochanteric Nail, Left, 10 mm x 39 cm x 130°	AR-9094-10-3930L
Long Trochanteric Nail, Right, 10 mm x 39 cm x 130°	AR-9094-10-3930R
Long Trochanteric Nail, Left, 10 mm x 42 cm x 130°	AR-9094-10-4230L
Long Trochanteric Nail, Right, 10 mm x 42 cm x 130°	AR-9094-10-4230R
Long Trochanteric Nail, Left, 10 mm x 45 cm x 130°	AR-9094-10-4530L
Long Trochanteric Nail, Right, 10 mm x 45 cm x 130°	AR-9094-10-4530R
Long Trochanteric Nail, Left, 11 mm x 30 cm x 125°	AR-9094-11-3025L
Long Trochanteric Nail, Right, 11 mm x 30 cm x 125°	AR-9094-11-3025R
Long Trochanteric Nail, Left, 11 mm x 33 cm x 125°	AR-9094-11-3325L
Long Trochanteric Nail, Right, 11 mm x 33 cm x 125°	AR-9094-11-3325R
Long Trochanteric Nail, Left, 11 mm x 36 cm x 125°	AR-9094-11-3625L
Long Trochanteric Nail, Right, 11 mm x 36 cm x 125°	AR-9094-11-3625R
Long Trochanteric Nail, Left, 11 mm x 39 cm x 125°	AR-9094-11-3925L
Long Trochanteric Nail, Right, 11 mm x 39 cm x 125°	AR-9094-11-3925R
Long Trochanteric Nail, Left, 11 mm x 42 cm x 125°	AR-9094-11-4225L
Long Trochanteric Nail, Right, 11 mm x 42 cm x 125°	AR-9094-11-4225R
Long Trochanteric Nail, Left, 11 mm x 45 cm x 125°	AR-9094-11-4525L
Long Trochanteric Nail, Right, 11 mm x 45 cm x 125°	AR-9094-11-4525R
Long Trochanteric Nail, Left, 11 mm x 30 cm x 130°	AR-9094-11-3030L
Long Trochanteric Nail, Right, 11 mm x 30 cm x 130°	AR-9094-11-3030R
Long Trochanteric Nail, Left, 11 mm x 33 cm x 130°	AR-9094-11-3330L

Product Description	Item Number
Long Trochanteric Nail, Right, 11 mm x 33 cm x 130°	AR-9094-11-3330R
Long Trochanteric Nail, Left, 11 mm x 36 cm x 130°	AR-9094-11-3630L
Long Trochanteric Nail, Right, 11 mm x 36 cm x 130°	AR-9094-11-3630R
Long Trochanteric Nail, Left, 11 mm x 39 cm x 130°	AR-9094-11-3930L
Long Trochanteric Nail, Right, 11 mm x 39 cm x 130°	AR-9094-11-3930R
Long Trochanteric Nail, Left, 11 mm x 42 cm x 130°	AR-9094-11-4230L
Long Trochanteric Nail, Right, 11 mm x 42 cm x 130°	AR-9094-11-4230R
Long Trochanteric Nail, Left, 11 mm x 45 cm x 130°	AR-9094-11-4530L
Long Trochanteric Nail, Right, 11 mm x 45 cm x 130°	AR-9094-11-4530R
Long Trochanteric Nail, Left, 12.5 mm x 30 cm x 130°	AR-9094-12-3030L
Long Trochanteric Nail, Right, 12.5 mm x 30 cm x 130°	AR-9094-12-3030R
Long Trochanteric Nail, Left, 12.5 mm x 33 cm x 130°	AR-9094-12-3330L
Long Trochanteric Nail, Right, 12.5 mm x 33 cm x 130°	AR-9094-12-3330R
Long Trochanteric Nail, Left, 12.5 mm x 36 cm x 130°	AR-9094-12-3630L
Long Trochanteric Nail, Right, 12.5 mm x 36 cm x 130°	AR-9094-12-3630R
Long Trochanteric Nail, Left, 12.5 mm x 39 cm x 130°	AR-9094-12-3930L
Long Trochanteric Nail, Right, 12.5 mm x 39 cm x 130°	AR-9094-12-3930R
Long Trochanteric Nail, Left, 12.5 mm x 42 cm x 130°	AR-9094-12-4230L
Long Trochanteric Nail, Right, 12.5 mm x 42 cm x 130°	AR-9094-12-4230R
Long Trochanteric Nail, Left, 12.5 mm x 45 cm x 130°	AR-9094-12-4530L
Long Trochanteric Nail, Right, 12.5 mm x 45 cm x 130°	AR-9094-12-4530R
ES Trochanteric Nail, Left, 10 mm x 30 cm x 125°	AR-9094ES-10-3025L
ES Trochanteric Nail, Right, 10 mm x 30 cm x 125°	AR-9094ES-10-3025R
ES Trochanteric Nail, Left, 10 mm x 33 cm x 125°	AR-9094ES-10-3325L
ES Trochanteric Nail, Right, 10 mm x 33 cm x 125°	AR-9094ES-10-3325R
ES Trochanteric Nail, Left, 10 mm x 36 cm x 125°	AR-9094ES-10-3625L
ES Trochanteric Nail, Right, 10 mm x 36 cm x 125°	AR-9094ES-10-3625R

Product Description	Item Number
ES Trochanteric Nail, Left, 10 mm x 39 cm x 125°	AR-9094ES-10-3925L
ES Trochanteric Nail, Right, 10 mm x 39 cm x 125°	AR-9094ES-10-3925R
ES Trochanteric Nail, Left, 10 mm x 42 cm x 125°	AR-9094ES-10-4225L
ES Trochanteric Nail, Right, 10 mm x 42 cm x 125°	AR-9094ES-10-4225R
ES Trochanteric Nail, Left, 10 mm x 45 cm x 125°	AR-9094ES-10-4525L
ES Trochanteric Nail, Right, 10 mm x 45 cm x 125°	AR-9094ES-10-4525R
ES Trochanteric Nail, Left, 10 mm x 30 cm x 130°	AR-9094ES-10-3030L
ES Trochanteric Nail, Right, 10 mm x 30 cm x 130°	AR-9094ES-10-3030R
ES Trochanteric Nail, Left, 10 mm x 33 cm x 130°	AR-9094ES-10-3330L
ES Trochanteric Nail, Right, 10 mm x 33 cm x 130°	AR-9094ES-10-3330R
ES Trochanteric Nail, Left, 10 mm x 36 cm x 130°	AR-9094ES-10-3630L
ES Trochanteric Nail, Right, 10 mm x 36 cm x 130°	AR-9094ES-10-3630R
ES Trochanteric Nail, Left, 10 mm x 39 cm x 130°	AR-9094ES-10-3930L
ES Trochanteric Nail, Right, 10 mm x 39 cm x 130°	AR-9094ES-10-3930R
ES Trochanteric Nail, Left, 10 mm x 42 cm x 130°	AR-9094ES-10-4230L
ES Trochanteric Nail, Right, 10 mm x 42 cm x 130°	AR-9094ES-10-4230R
ES Trochanteric Nail, Left, 10 mm x 45 cm x 130°	AR-9094ES-10-4530L
ES Trochanteric Nail, Right, 10 mm x 45 cm x 130°	AR-9094ES-10-4530R
ES Trochanteric Nail, Left, 11 mm x 30 cm x 125°	AR-9094ES-11-3025L
ES Trochanteric Nail, Right, 11 mm x 30 cm x 125°	AR-9094ES-11-3025R
ES Trochanteric Nail, Left, 11 mm x 33 cm x 125°	AR-9094ES-11-3325L
ES Trochanteric Nail, Right, 11 mm x 33 cm x 125°	AR-9094ES-11-3325R
ES Trochanteric Nail, Left, 11 mm x 36 cm, 125°	AR-9094ES-11-3625L
ES Trochanteric Nail, Right, 11 mm x 36 cm x 125°	AR-9094ES-11-3625R
ES Trochanteric Nail, Left, 11 mm x 39 cm x 125°	AR-9094ES-11-3925L
ES Trochanteric Nail, Right, 11 mm x 39 cm x 125°	AR-9094ES-11-3925R
ES Trochanteric Nail, Left, 11 mm x 42 cm x 125°	AR-9094ES-11-4225L

Product Description	Item Number
ES Trochanteric Nail, Right, 11 mm x 42 cm x 125°	AR-9094ES-11-4225R
ES Trochanteric Nail, Left, 11 mm x 45 cm x 125°	AR-9094ES-11-4525L
ES Trochanteric Nail, Right, 11 mm x 45 cm x 125°	AR-9094ES-11-4525R
ES Trochanteric Nail, Left, 11 mm x 30 cm x 130°	AR-9094ES-11-3030L
ES Trochanteric Nail, Right, 11 mm x 30 cm x 130°	AR-9094ES-11-3030R
ES Trochanteric Nail, Left, 11 mm x 33 cm x 130°	AR-9094ES-11-3330L
ES Trochanteric Nail, Right, 11 mm x 33 cm x 130°	AR-9094ES-11-3330R
ES Trochanteric Nail, Left, 11 mm x 36 cm x 130°	AR-9094ES-11-3630L
ES Trochanteric Nail, Right, 11 mm x 36 cm x 130°	AR-9094ES-11-3630R
ES Trochanteric Nail, Left, 11 mm x 39 cm x 130°	AR-9094ES-11-3930L
ES Trochanteric Nail, Right, 11 mm x 39 cm x 130°	AR-9094ES-11-3930R
ES Trochanteric Nail, Left, 11 mm x 42 cm x 130°	AR-9094ES-11-4230L
ES Trochanteric Nail, Right, 11 mm x 42 cm x 130°	AR-9094ES-11-4230R
ES Trochanteric Nail, Left, 11 mm x 45 cm x 130°	AR-9094ES-11-4530L
ES Trochanteric Nail, Right, 11 mm x 45 cm x 130°	AR-9094ES-11-4530R
ES Trochanteric Nail, Left, 12.5 mm x 30 cm x 130°	AR-9094ES-12-3030L
ES Trochanteric Nail, Right, 12.5 mm x 30 cm x 130°	AR-9094ES-12-3030R
ES Trochanteric Nail, Left, 12.5 mm x 33 cm x 130°	AR-9094ES-12-3330L
ES Trochanteric Nail, Right, 12.5 mm x 33 cm x 130°	AR-9094ES-12-3330R
ES Trochanteric Nail, Left, 12.5 mm x 36 cm x 130°	AR-9094ES-12-3630L
ES Trochanteric Nail, Right, 12.5 mm x 36 cm x 130°	AR-9094ES-12-3630R
ES Trochanteric Nail, Left, 12.5 mm x 39 cm x 130°	AR-9094ES-12-3930L
ES Trochanteric Nail, Right, 12.5 mm x 39 cm x 130°	AR-9094ES-12-3930R
ES Trochanteric Nail, Left, 12.5 mm x 42 cm x 130°	AR-9094ES-12-4230L
ES Trochanteric Nail, Right, 12.5 mm x 42 cm x 130°	AR-9094ES-12-4230R
ES Trochanteric Nail, Left, 12.5 mm x 45 cm x 130°	AR-9094ES-12-4530L
ES Trochanteric Nail, Right, 12.5 mm x 45 cm x 130°	AR-9094ES-12-4530R

Product Description	Item Number
ES Trochanteric Nail, Left, 12.5 mm x 30 cm x 125°	AR-9094ES-12-3025L
ES Trochanteric Nail, Right, 12.5 mm x 30 cm x 125°	AR-9094ES-12-3025R
ES Trochanteric Nail, Left, 12.5 mm x 33 cm x 125°	AR-9094ES-12-3325L
ES Trochanteric Nail, Right, 12.5 mm x 33 cm x 125°	AR-9094ES-12-3325R
ES Trochanteric Nail, Left, 12.5 mm x 36 cm x 125°	AR-9094ES-12-3625L
ES Trochanteric Nail, Right, 12.5 mm x 36 cm x 125°	AR-9094ES-12-3625R
ES Trochanteric Nail, Left, 12.5 mm x 39 cm x 125°	AR-9094ES-12-3925L
ES Trochanteric Nail, Left, 12.5 mm x 39 cm x 125°	AR-9094ES-12-3925R
ES Trochanteric Nail, Left, 12.5 mm x 42 cm x 125°	AR-9094ES-12-4225L
ES Trochanteric Nail, Right, 12.5 mm x 42 cm x 125°	AR-9094ES-12-4225R
ES Trochanteric Nail, Left, 12.5 mm x 45 cm x 125°	AR-9094ES-12-4525L
ES Trochanteric Nail, Right, 12.5 mm x 45 cm x 125°	AR-9094ES-12-4525R
ES Trochanteric Nail, Left, 14 mm x 30 cm x 130°	AR-9094ES-14-3030L
ES Trochanteric Nail, Right, 14 mm x 30 cm x 130°	AR-9094ES-14-3030R
ES Trochanteric Nail, Left, 14 mm x 33 cm x 130°	AR-9094ES-14-3330L
ES Trochanteric Nail, Right, 14 mm x 33 cm x 130°	AR-9094ES-14-3330R
ES Trochanteric Nail, Left, 14 mm x 36 cm x 130°	AR-9094ES-14-3630L
ES Trochanteric Nail, Right, 14 mm x 36 cm x 130°	AR-9094ES-14-3630R
ES Trochanteric Nail, Left, 14 mm x 39 cm x 130°	AR-9094ES-14-3930L
ES Trochanteric Nail, Right, 14 mm x 39 cm x 130°	AR-9094ES-14-3930R
ES Trochanteric Nail, Left, 14 mm x 42 cm x 130°	AR-9094ES-14-4230L
ES Trochanteric Nail, Right, 14 mm x 42 cm x 130°	AR-9094ES-14-4230R
ES Trochanteric Nail, Left, 14 mm x 45 cm x 130°	AR-9094ES-14-4530L
ES Trochanteric Nail, Right, 14 mm x 45 cm x 130°	AR-9094ES-14-4530R

Trochanteric Nail Implant System

Interlocking Screw Implant Models

Product Description	Item Number
Cortical Screw, Captured, 5.0 x 20 mm	AR-9093-50-020
Cortical Screw, Captured, 5.0 x 22 mm	AR-9093-50-022
Cortical Screw, Captured, 5.0 x 24 mm	AR-9093-50-024
Cortical Screw, Captured, 5.0 x 26 mm	AR-9093-50-026
Cortical Screw, Captured, 5.0 x 28 mm	AR-9093-50-028
Cortical Screw, Captured, 5.0 x 30 mm	AR-9093-50-030
Cortical Screw, Captured, 5.0 x 32 mm	AR-9093-50-032
Cortical Screw, Captured, 5.0 x 34 mm	AR-9093-50-034
Cortical Screw, Captured, 5.0 x 36 mm	AR-9093-50-036
Cortical Screw, Captured, 5.0 x 38 mm	AR-9093-50-038
Cortical Screw, Captured, 5.0 x 40 mm	AR-9093-50-040
Cortical Screw, Captured, 5.0 x 42 mm	AR-9093-50-042
Cortical Screw, Captured, 5.0 x 44 mm	AR-9093-50-044
Cortical Screw, Captured, 5.0 x 46 mm	AR-9093-50-046
Cortical Screw, Captured, 5.0 x 48 mm	AR-9093-50-048
Cortical Screw, Captured, 5.0 x 50 mm	AR-9093-50-050
Cortical Screw, Captured, 5.0 x 55 mm	AR-9093-50-055
Cortical Screw, Captured, 5.0 x 60 mm	AR-9093-50-060
Cortical Screw, Captured, 5.0 x 65 mm	AR-9093-50-065
Cortical Screw, Captured, 5.0 x 70 mm	AR-9093-50-070
Cortical Screw, Captured, 5.0 x 75 mm	AR-9093-50-075
Cortical Screw, Captured, 5.0 x 80 mm	AR-9093-50-080
Cortical Screw, Captured, 5.0 x 85 mm	AR-9093-50-085
Cortical Screw, Captured, 5.0 x 90 mm	AR-9093-50-090

Product Description	Item Number
Cortical Screw, Captured, 5.0 x 95 mm	AR-9093-50-095
Cortical Screw, Captured, 5.0 x 100 mm	AR-9093-50-100
Cortical Screw, Captured, 5.0 x 105 mm	AR-9093-50-105
Cortical Screw, Captured, 5.0 x 110 mm	AR-9093-50-110
Cortical Screw, Captured, 5.0 x 115 mm	AR-9093-50-115
Cortical Screw, Captured, 5.0 x 120 mm	AR-9093-50-120
Lag Screw, 10.5 x 80 mm	AR-9094-0080
Lag Screw, 10.5 x 85 mm	AR-9094-0085
Lag Screw, 10.5 x 90 mm	AR-9094-0090
Lag Screw, 10.5 x 95 mm	AR-9094-0095
Lag Screw, 10.5 x 100 mm	AR-9094-0100
Lag Screw, 10.5 x 105 mm	AR-9094-0105
Lag Screw, 10.5 x 110 mm	AR-9094-0110
Lag Screw, 10.5 x 115 mm	AR-9094-0115
Lag Screw, 10.5 x 120 mm	AR-9094-0120
Lag Screw, 10.5 x 125 mm	AR-9094-0125
Telescoping Lag Screw, 10.5 x 80 mm	AR-9094-080
Telescoping Lag Screw, 10.5 x 85 mm	AR-9094-085
Telescoping Lag Screw, 10.5 x 90 mm	AR-9094-090
Telescoping Lag Screw, 10.5 x 95 mm	AR-9094-095
Telescoping Lag Screw, 10.5 x 100 mm	AR-9094-100
Telescoping Lag Screw, 10.5 x 105 mm	AR-9094-105
Telescoping Lag Screw, 10.5 x 110 mm	AR-9094-110
Telescoping Lag Screw, 10.5 x 115 mm	AR-9094-115
Telescoping Lag Screw, 10.5 x 120 mm	AR-9094-120
Telescoping Lag Screw, 10.5 x 125 mm	AR-9094-125
Telescoping Lag Screw, Left Threaded, 80 mm	AR-9094-080L

Product Description	Item Number
Telescoping Lag Screw, Left Threaded, 85 mm	AR-9094-085L
Telescoping Lag Screw, Left Threaded, 90 mm	AR-9094-090L
Telescoping Lag Screw, Left Threaded, 95 mm	AR-9094-095L
Telescoping Lag Screw, Left Threaded, 100 mm	AR-9094-100L
Telescoping Lag Screw, Left Threaded, 105 mm	AR-9094-105L
Telescoping Lag Screw, Left Threaded, 110 mm	AR-9094-110L
Telescoping Lag Screw, Left Threaded, 115 mm	AR-9094-115L
Telescoping Lag Screw, Left Threaded, 120 mm	AR-9094-120L
Telescoping Lag Screw, Left Threaded, 125 mm	AR-9094-125L
Solid Locking Lag Screw, 10.5 x 70 mm	AR-9094-1070
Solid Locking Lag Screw, 10.5 x 75 mm	AR-9094-1075
Solid Locking Lag Screw, 10.5 x 80 mm	AR-9094-1080
Solid Locking Lag Screw, 10.5 x 85 mm	AR-9094-1085
Solid Locking Lag Screw, 10.5 x 90 mm	AR-9094-1090
Solid Locking Lag Screw, 10.5 x 95 mm	AR-9094-1095
Solid Locking Lag Screw, 10.5 x 100 mm	AR-9094-1100
Solid Locking Lag Screw, 10.5 x 105 mm	AR-9094-1105
Solid Locking Lag Screw, 10.5 x 110 mm	AR-9094-1110
Solid Locking Lag Screw, 10.5 x 115 mm	AR-9094-1115
Solid Locking Lag Screw, 10.5 x 120 mm	AR-9094-1120
Solid Locking Lag Screw, 10.5 x 125 mm	AR-9094-1125
Anti-Rotation Screw, 5.0 x 55 mm	AR-9094AR-055
Anti-Rotation Screw, 5.0 x 60 mm	AR-9094AR-060
Anti-Rotation Screw, 5.0 x 65 mm	AR-9094AR-065
Anti-Rotation Screw, 5.0 x 70 mm	AR-9094AR-070
Anti-Rotation Screw, 5.0 x 75 mm	AR-9094AR-075
Anti-Rotation Screw, 5.0 x 80 mm	AR-9094AR-080
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Product Description	Item Number
Anti-Rotation Screw, 5.0 x 85 mm	AR-9094AR-085
Anti-Rotation Screw, 5.0 x 90 mm	AR-9094AR-090
Anti-Rotation Screw, 5.0 x 95 mm	AR-9094AR-095
Anti-Rotation Screw, 5.0 x 100 mm	AR-9094AR-100
Anti-Rotation Screw, 5.0 x 105 mm	AR-9094AR-105
Anti-Rotation Screw, 5.0 x 110 mm	AR-9094AR-110
End Cap, Captured, Bullet Tip, 1 mm, Trochanteric Nail	AR-9094C-01
End Cap, Captured, Bullet Tip, 5 mm, Trochanteric Nail	AR-9094C-05
End Cap, Captured, Bullet Tip, 10 mm, Trochanteric Nail	AR-9094C-10
Locking End Cap, 1 mm, Trochanteric Nail	AR-9094CP-01

Contact Information

Any serious incident that occurs in relation to the device should be reported to the manufacturer and to the health authority where the incident occurred.

Region	Contact
Arthrex, Inc.	1370 Creekside Blvd. Naples, FL 34108, USA ✓ +1 800 934-4404 <u>arthrex.com</u>
EC REP Arthrex GmbH	Erwin-Hielscher-Strasse 9 81249 München, Germany +49 89 90 90 05-0 <u>arthrex.de</u>
Arthrex Distribution Hub EMEA B.V.	Ampèrestraat 9 5928 PE Venlo, Netherlands +31 88 712 9800 arthrex.nl
UK REP Arthrex Ltd.,	Unit 1 Bessemer Park Shepcote Lane Sheffield S9 1DZ United Kingdom +44 0 114 232 9180 arthrex.co.uk
CH REP confinis ch-rep ag,	Hauptstrasse 16 3186 Düdingen, Switzerland • +41 26 494 8 494
Manufacturer's Australian Sponsor Arthrex Australia Pty Ltd	Suite 501, 20 Rodborough Road Frenchs Forest, NSW, 2086 Australia +1 800 950 637 arthrex.com.au

USA – U. S. Food & Drug Administration website: <u>https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program</u>

Australia – Therapeutic Goods Administration website: https://www.tga.gov.au

European Union – https://ec.europa.eu/growth/sectors/medical-devices/contacts_en

Symbols glossary can be found at <u>www.arthrex.com/symbolsglossary</u>.



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